DEC 2 0 2000

K003781

Premarket Notification 510(k) Summary CoolTouch "Varia-II" Nd:YAG Laser System

This 510(K) Summary of safety and effectiveness for the CoolTouch "Varia-II" Nd:YAG surgical laser system is submitted in accordance with the requirements of 21 CFR 807.92.

Applicant:	CoolTouch Corporation
Address:	9085 Foothills Boulevard Roseville, CA 95747
Contact Person:	Donald V. Johnson
Telephone:	(916) 677-1900
Fax:	(916) 677-1901
Preparation Date:	December 5, 2000
Device Trade Name:	CoolTouch "Varia-II" Nd:YAG Surgical Laser
Common Name:	Nd:YAG Pulsed Surgical Laser
Classification Name:	Instrument, Surgical Powered, Laser 79-GEX
Legally Marketed Predicate Device:	Laser Aesthetics CoolTouch "V" Nd:YAG Laser System
Description of the CoolTouch Corporation CoolTouch "Varia-II" Nd:YAG Surgical Laser:	The CoolTouch Corporation CoolTouch "Varia-II" Nd:YAG Surgical Laser is a laser producing emissions at 1064nm. The laser consists of several interconnected sections: the *cabinet*, which houses the power supply, cooling system, microcontroller, and the laser head, the *fiber optics*, and the *handpiece*.

Technical Specification Comparison

Specification	Laser Aesthetics, Inc. Nd:YAG Surgical Laser Model CoolTouch "V" Pulsed Laser System	CoolTouch Corporation Nd:YAG Surgical Laser Model "Varia II" Pulsed Laser System
Laser Medium	Nd:YAG 1064nm	Same
Pulse Duration	400 μsec	Same
Pulse Repetition Rate	1 burst per second (1 Hz)	2 bursts per second (2 Hz)
Power	6 watts minimum 36 watts maximum	6 watts minimum 60 watts maximum
Exposure	6 pulses per burst	Same
Energy per Pulse	Variable to 6 joules	Same
Energy per Pulse	Variable to 6 joules	Same
Aiming Beam	0.5 mw Diode @ 630-640 nm	Same
Beam Delivery	Standard: Model 1430 Cooling Handpiece	Same
Dimensions	31"H x 18"W x 21"D 79 x 46 x 53 cm	Same
Weight	160 lbs (73kg) console	Same
Power Requirements	115 VAC, 50/60 Hz, 15A, single phase 230 VAC, 50/60 Hz, 10A, single phase	220 VAC, 50/60 Hz, 15A, single phase
Safety	Standard Nd:YAG Eyewear, Remote Interlock Connector, Removable Key	Same
Energy Monitor	Calibrated display indicates energy delivered to tissue in Joules	Same
Fiber Calibration	Integral power/energy meter to verify fiber transmission	Same
Indications	Coagulation and hemostasis of vascular lesions and soft tissue.	Same

Intended use of the CootTouch Corporation CoolTouch "Varia-II" Nd:YAG Surgical Laser:	The CoolTouch "Varia-II" Nd:YAG Surgical Laser is indicated for the coagulation and hemostasis of vascular lesions and soft tissue.
Nonclinical Performance Data:	None.
Clinical Performance Data:	None.
Conclusion:	The CoolTouch "Varia-II" Nd:YAG Surgical Laser System is substantially equivalent to the Laser Aesthetics CoolTouch "V" Nd"YAG Surgical Laser System in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Donald V. Johnson
Director, Regulatory and Quality Affairs
CoolTouch Corporation
9085 Foothills Boulevard
Roseville, California 95747

DEC 2 0 2000

Re: K003781
Trade Name: CoolTouch Varia-II
Regulatory Class: II
Product Code: GEX
Dated: December 5, 2000
Received: December 7, 2000

Dear Mr. Johnson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number Pending K003781

Device Name CoolTouch Varia-II

Indications for Use The CoolTouch Corporation Nd:YAG Surgical Laser Model CoolTouch "Varia-II" is indicated for the coagulation and hemostasis of vascular lesions and soft tissue.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

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of General Restorative Devices
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